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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. | |
|-----------------------|---------------------------------------|-------------------------|---------------------|------------------|--|
| 10/655,595 | 09/05/2003 | Bernd Christoph Lang | 4398-254 | 7314 | |
| 23117 | 7590 06/28/2005 | 06/28/2005 | | EXAMINER | |
| NIXON & VANDERHYE, PC | | | MITCHELL, TEENA KAY | | |
| ARLINGTON | GLEBE ROAD, 11TH F ', VA 22203 | LOOK . | ART UNIT | PAPER NUMBER | |
| | | | 3743 | | |
| | | DATE MAILED: 06/20/2005 | | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

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| | Application No. | Applicant(s) | | | | |
|---|--|--|--|--|--|--|
| O#' A-4' O | 10/655,595 | LANG ET AL. | | | | |
| Office Action Summary | Examiner | Art Unit | | | | |
| | Teena Mitchell | 3743 | | | | |
| The MAILING DATE of this communication app Period for Reply | ears on the cover sheet with the c | orrespondence address | | | | |
| A SHORTENED STATUTORY PERIOD FOR REPLY THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a reply If NO period for reply is specified above, the maximum statutory period was a Failure to reply within the set or extended period for reply will, by statute, Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b). | 6(a). In no event, however, may a reply be time within the statutory minimum of thirty (30) days ill apply and will expire SIX (6) MONTHS from cause the application to become ABANDONE | nety filed s will be considered timety. the mailing date of this communication. D (35 U.S.C. § 133). | | | | |
| Status | | | | | | |
| 1) Responsive to communication(s) filed on <u>05 Se</u> | eptember 2003. | | | | | |
| 2a) ☐ This action is FINAL . 2b) ☑ This | | | | | | |
| • | 3) Since this application is in condition for allowance except for formal matters, prosecution as to the ments is | | | | | |
| closed in accordance with the practice under E | x parte Quayle, 1935 C.D. 11, 45 | 53 O.G. 213. | | | | |
| Disposition of Claims | | | | | | |
| 4) Claim(s) <u>1-67</u> is/are pending in the application. | | | | | | |
| 4a) Of the above claim(s) is/are withdraw | vn from consideration. | | | | | |
| 5) Claim(s) is/are allowed. | | | | | | |
| 6) Claim(s) <u>1,2,6-42 and 46-67</u> is/are rejected. | 6) Claim(s) <u>1,2,6-42 and 46-67</u> is/are rejected. | | | | | |
| 7) Claim(s) <u>3-5 and 43-45</u> is/are objected to. | | | | | | |
| 8) Claim(s) are subject to restriction and/or | r election requirement. | | | | | |
| Application Papers | | | | | | |
| 9) The specification is objected to by the Examine | r. | | | | | |
| 10)⊠ The drawing(s) filed on 05 September 2003 is/a | 10)⊠ The drawing(s) filed on <u>05 September 2003</u> is/are: a) accepted or b)⊠ objected to by the Examiner. | | | | | |
| Applicant may not request that any objection to the | | | | | | |
| • | Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). | | | | | |
| 11)☐ The oath or declaration is objected to by the Ex | aminer. Note the attached Office | Action or form PTO-152. | | | | |
| Priority under 35 U.S.C. § 119 | | | | | | |
| 12) ☐ Acknowledgment is made of a claim for foreign a) ☐ All b) ☐ Some * c) ☐ None of: | priority under 35 U.S.C. § 119(a) |)-(d) or (f). | | | | |
| Certified copies of the priority documents | s have been received. | | | | | |
| 2. Certified copies of the priority documents | | | | | | |
| 3. Copies of the certified copies of the prior | | ed in this National Stage | | | | |
| application from the International Bureau (PCT Rule 17.2(a)). | | | | | | |
| * See the attached detailed Office action for a list of the certified copies not received. | | | | | | |
| Attachment(s) | | | | | | |
| 1) Notice of References Cited (PTO-892) | 4) Interview Summary | | | | | |
| 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | Paper No(s)/Mail Da 5) Notice of Informal P | ate Patent Application (PTO-152) | | | | |
| 3) [X] Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 9/5/03;11/26/03;6 m 05 | 6) Other: | | | | | |

DETAILED ACTION

Drawings

Figures 16 and 17 should be designated by a legend such as --Prior Art--because only that which is old is illustrated. See MPEP § 608.02(g). Corrected drawings in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. The replacement sheet(s) should be labeled "Replacement Sheet" in the page header (as per 37 CFR 1.84(c)) so as not to obstruct any portion of the drawing figures. If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: lip 310, lip 311, and lines of force 490. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

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Claim Objections

Claim 29 objected to because of the following informalities: , line 2, "...the lines of force..." lacks antecedent basis. Correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors

Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology

Technical Amendments Act of 2002 do not apply when the reference is a U.S.

patent resulting directly or indirectly from an international application filed before

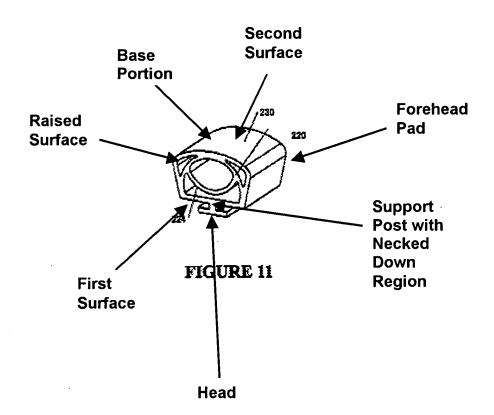
November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1-3, 11, 28-31, 33-36, 54-59, 61, and 65-67 are rejected under 35 U.S.C. 102(e) as being anticipated by Gradon et.al. (6,832,610).

Gradon in a respiratory mask discloses: a base portion (see illustration of Fig. 11 below), wherein the base portion defines a first surface, and a second surface to contact a user's forehead, wherein the second surface is concave (see illustration of Fig. 11

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below); a support post, wherein the support post projects from the first surface and comprises a necked down region; and a head adapted to connect the support post to a forehead support of a respiratory mask (Fig. 7).



With respect to claim 2, Gradon discloses wherein the support post projects from the base portion and is integrally molded therewith (See illustration of Fig. 11 above).

With respect to claim 3, Gradon discloses wherein the second surface defines a raised surface pattern to at least one of aid in airflow, prevent sweating, and increase comfort to the user (see illustration of Fig. 11 above; inasmuch as the raised surface compresses and has an opening it meets the limitations of aiding in airflow, preventing sweating and increasing comfort to a user).

With respect to claim 11, Gradon discloses wherein the support post is axially compressible (inasmuch as the material is a silicone the support post is inherently axially compressible upon use of the device, (Col. 5, lines 6-10).

With respect to claim 28, Gradon discloses wherein the head is adapted to be realeasably connected to the forehead support using a push-on motion (Col. 6, lines 1-5).

With respect to claim 29, Gradon discloses wherein the support post is sufficiently rigid to distribute the lines of force from the forehead support evenly across the second surface of the forehead pad (Col. 5, lines 6-10).

With respect to claim 30, Gradon discloses wherein the support post and the base portion are configured to evenly distribute forces across the second surface without localized pressure points (Figs. 8A, 8B, 9, 11).

With respect to claim 31, Gradon discloses wherein the forehead pad consists of the base portion, the support post, and the head (Figs. 8-11, see illustration of Fig. 11 above).

With respect to claim 33, Gradon discloses a forehead support consisting essentially of a base portion to contact a user's forehead; and a support post connected to a central portion of the base portion (see illustration of Fig. 11 above, MPEP 211.03 the additional elements of Gradon do not materially effect the basic and novel characteristics of the claimed invention).

With respect to claim 34, Gradon discloses wherein the support post is substantially centrally mounted on the base portion (see illustration of Fig. 11 above).

With respect to claim 35, Gradon discloses a base portion to contact a user's forehead (Figs. 8-11, see illustration of Fig. 11 above); a support post connected to the base portion; and a head adapted to connect the support post to a forehead support of a respiratory mask (Figs. 7-11), wherein the support post distributes lines of force from the head through the support post to the base portion such that the lines of force are substantially evenly distributed across the base portion (Figs. 7-11).

With respect to claim 36, Gradon discloses a respiratory mask (Figs. 2, 7-11), a forehead support having an aperture and an otherwise entirely smooth surface facing a user in use of the mask (Fig. 7); and a forehead pad comprising a base portion, wherein the base portion defines a first surface and a second surface opposite the first surface to contact a user's forehead, a support post, wherein the support post projects from the first surface, and a head adapted to connect the support post to the forehead support (Figs. 7-11; see illustration of Fig. 11 above).

With respect to claim 54, Gradon discloses a respiratory mask (Fig. 2) comprising a forehead support (Figs.2, 7, 12); and a forehead pad comprising: a base

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portion, wherein the base portion further defines a first surface, and a second surface to contact a user's forehead, wherein the second surface is concave; a support post, wherein the support post projects from the first surface and comprises a necked down region; and a head adapted to connect the support post to a forehead support (Figs. 7-11; see illustration of Fig. 11 above).

With respect to claim 55, Gradon discloses wherein the forehead support is essentially straight (Figs. 7, 12).

With respect to claim 56, Gradon discloses wherein the forehead support is curved (Figs. 7, 12).

With respect to claim 57, Gradon discloses wherein the forehead pad connected to the forehead support does not project a hard surface to the user's forehead (Figs. 7-12).

With respect to claim 58, Gradon discloses wherein the forehead pad is secured to the forehead support by only the support post (Figs. 7-12; see illustration of Fig. 11 above).

With respect to claim 59, Gradon discloses wherein the support post is axially compressible (inasmuch as the material is a silicone the support post is inherently axially compressible upon use of the device, (Col. 5, lines 6-10).

With respect to claim 61, Gradon discloses wherein the forehead support includes at least one aperture (Figs. 7, 12).

With respect to claim 65, Gradon discloses a forehead support (Figs. 7, 12); and a forehead pad comprising; a base portion, wherein the base portion further defines: a

first surface, and a second surface to contact a user's forehead; a support post, wherein the support post projects from the first surface and is adapted to connect to the forehead support, wherein the base portion is connected to the forehead support solely through the support post (Figs. 7-12; see illustration of Fig. 11 above).

With respect to claim 66, Gradon discloses wherein a surface of the forehead support that faces the forehead pad includes no protrusions (Figs.7-12).

With respect to claim 67, Gradon discloses a forehead pad comprising: a base portion, wherein the base portion further defines: a first surface, and a second surface to contact a user's forehead; a support post, wherein the support post projects from the first surface and is adapted to connect to the forehead support, wherein the second surface substantially evenly distributes force across the forehead pad without localized pressure points (Figs. 7-12).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1, 2, 6-12, 18, 28-42, and 46-67 are rejected under 35 U.S.C. 102(a) as being anticipated by Lang (DE 100,45,183 A1).

Lang in a forehead pad discloses a base portion, wherein the base portion defines a first surface, and a second surface to contact a user's forehead, wherein the

second surface is concave (Figs. 1-4); a support post, wherein the support post projects from the first surface and comprises a necked down region (Figs. 2, 4); and a head adapted to connect the support post to a forehead support of a respiratory mask (Figs. 1-4).

With respect to claim 2, Lang discloses wherein the support post projects from the base portion and is integrally molded therewith (Figs. 1-4).

With respect to claim 6, Lang discloses wherein the second surface defines a raised surface pattern to at least one of aid in airflow, preventing sweating, and increase comfort to the user (Figs. 2-4).

With respect to claim 7, Lang discloses wherein the base portion and support post include a hollowed out region extending a pre-determined distance into at least one of the base portion and support post (Fig. 2-4).

With respect to claim 8, Lang discloses wherein the support post includes a tapered portion such that a region at the base portion is thicker than the head (Figs. 2-4).

With respect to claim 9, Lang discloses wherein the head includes a tapered portion from the support post to a point (Figs. 2-4).

With respect to claim 10, Lang discloses wherein the diameter of the necked down region is less than the diameter of a base of the head (Figs. 2-4).

With respect to claim 11, Lang discloses wherein the support post is axially compressible (Abstract).

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With respect to claim 12, Lang discloses wherein the support post includes at least one cut away portion (Figs. 2-4).

With respect to claim 18, Lang discloses wherein the support post further includes at least one undercut (Figs. 2-4).

With respect to claim 28, Lang discloses wherein the head is adapted to be releasably connected to the forehead support using a push-on motion (Figs. 1-4; Abstract).

With respect to claim 29, Lang discloses wherein the support post is sufficiently rigid to distribute the lines of force from the forehead support evenly across the second surface of the forehead pad (Figs. 1-4; Abstract).

With respect to claim 30, Lang discloses wherein the support post and the base portion are configured to evenly distribute forces across the second surface without localized pressure points (Figs. 1-4; Abstract).

With respect to claim 31, Lang discloses wherein the forehead pad consists of the base portion, the support post, and the head (Figs. 1-4).

With respect to claim 32, Lang discloses wherein the second surface consists essentially of the support post, which is substantially centrally mounted on the second surface (Figs. 2-4).

With respect to claim 33, Lang discloses a forehead pad consisting essentially of a base portion to contact a user's forehead; and a support post connected to a central portion of the base portion (Figs. 2-4).

With respect to claim 34, Lang discloses wherein the support post is substantially centrally mounted on the base portion (Figs. 1-4).

With respect to claim 35, Lang discloses a forehead pad comprising a base portion to contact a user's forehead; a support post connected to the base portion; and a head adapted to connect the support post to a forehead support of a respiratory mask, wherein the support post distributes lines of force from the head through the support post to the base portion such that the lines of force are substantially evenly distributed across the base portion (Figs. 1-4; Abstract).

With respect to claim 36, Lang discloses a respiratory mask (Fig. 1) comprising a forehead support having an aperture and an otherwise entirely smooth surface facing a user in use of the mask; and a forehead pad comprising a base portion, wherein the base portion defines a first surface and a second surface opposite the first surface to contact a user's forehead; a support post, wherein the support post projects from the first surface; and a head adapted to connect the support post to the forehead support (Figs. 1-4).

With respect to claim 37, Lang discloses wherein the assembly further comprises at least one connector to connect adjacent base portions (Fig. 3).

With respect to claim 38, Lang discloses wherein each base portion is adapted to be disposed above an eyebrow of the user (Figs. 1-4).

With respect to claim 40, Lang discloses wherein at least two base portion and at least one connector are integrally formed with each other (Figs. 1-4).

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With respect to claim 41, Lang discloses wherein at least one base portion and at least one connector are formed as one piece (Figs. 1-4).

With respect to claim 42, Lang discloses wherein the base portion defines a first surface, from which the support post projects (Figs. 1-4).

With respect to claim 46, Lang discloses wherein each base portion defines a second surface that is adapted to contact the user's forehead, and wherein the second surface is concave (Figs. 1-4).

With respect to claim 47, Lang discloses wherein the second surface defines a raised surface pattern to at least one of aid in airflow, prevent sweating, and increase comfort to the user (Figs. 1-4).

With respect to claim 48, Lang discloses wherein each base portion and support post include a hollowed out region extending a pre-determined distance into at least one of the base portion and support post (Figs. 2-4).

With respect to claim 49, Lang discloses wherein the support post includes a tapered portion such that a region at the base portion is thicker than the head (Figs. 2-4).

With respect to claim 50, Lang discloses wherein the head includes a tapered portion from the support post to a point (Figs. 2-4).

With respect to claim 51, Lang discloses wherein the diameter of the necked down region is less than the diameter of a base of the head (Figs. 2-4).

With respect to claim 52, Lang discloses wherein the support post is axially compressible (Abstract; Figs. 2-4).

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With respect to claim 53, Lang discloses wherein the support post includes cut away portions (Figs. 2-4).

With respect to claim 54, Lang discloses a respiratory mask comprising: a forehead support; and a forehead pad comprising: a base portion, wherein the base portion further defines a first surface, and a second surface to contact a user's forehead, wherein the second surface is concave; a support post, wherein the support post projects from the first surface and comprises a necked down region; and a head adapted to connect the support post to a forehead support (Figs. 1-4).

With respect to claim 55, Lang discloses wherein the forehead support is essentially straight (Figs. 1-4).

With respect to claim 56, Lang discloses wherein the forehead support is curved (Figs. 1-4).

With respect to claim 57, Lang discloses wherein the forehead pad connected to the forehead support does not project a hard surface to the user's forehead (Figs. 1-4).

With respect to claim 58, Lang discloses wherein the forehead pad is secured to the forehead support by only the support post (Figs. 1-4).

With respect to claim 59, Lang discloses wherein the support post is axially compressible (Abstract; Figs. 1-4).

With respect to claim 60, Lang discloses wherein the support post includes cut away portions (Figs. 1-4).

With respect to claim 61, Lang discloses wherein the forehead support includes at least one aperture (Figs. 1-4).

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With respect to claim 62, Lang discloses wherein the forehead support comprises compressible regions in proximity with the aperture (Figs. 1-4).

With respect to claim 63, Lang discloses wherein the head includes a tapered portion from the support post to a point in order to releasably insert the head in the aperture (Figs. 1-4).

With respect to claim 64, Lang discloses wherein the diameter of the necked down region is less than the diameter of a base of the head; such that the head can be releasably inserted into the aperture in order to securely attach the forehead pad to the forehead support (Figs. 1-4).

With respect to claim 65, Lang discloses a respiratory mask comprising: a forehead support; and a forehead pad comprising: a base portion, wherein the base portion further defines: a first surface, a second surface to contact a user's forehead: a support post, wherein the support post projects from the first surface and is adapted to connect to the forehead support; wherein the base portion is connected to the forehead support solely through the support post (Figs. 1-4).

With respect to claim 66, Lang discloses wherein a surface of the forehead support that faces the forehead pad includes no protrusions (Figs. 1-4).

With respect to claim 67, Lang discloses a forehead pad comprising: a base portion, wherein the base portion further defines: a first surface, and a second surface to contact a user's forehead; a support post, wherein the support post projects from the first surface and is adapted to connect to the forehead support, wherein the second

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surface substantially evenly distributes force across the forehead pad without localized pressure points (Figs. 1-4).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

- 1. Determining the scope and contents of the prior art.
- 2. Ascertaining the differences between the prior art and the claims at issue.
- 3. Resolving the level of ordinary skill in the pertinent art.
- 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary.

Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of

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35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 13-17, 19-27 rejected under 35 U.S.C. 103(a) as being unpatentable over Lang (DE 100,45,183 A1).

The difference between Lang and claim 13 is the length of the at least one cut away portion of between 0.05 mm to about 1.5 mm. It would have been an obvious matter of design consideration to one of ordinary skill in the art at the time the invention was made to have the length of the cut away portion of between 0.05 mm to about 1.5 mm because different users would require different length in order to have the forehead pad to be positioned properly on a user (i.e., an infant would require a different length than a teenager, therefore based on the user one of ordinary skill in the art could arrive at the claimed length ranges). Accordingly, the length of the cut away portion of between 0.05 mm to about 1.5 mm is deemed to be a design consideration, which fails to patentably distinguish over the prior art of Lang. Also applicant discloses that one skilled in the art can deviate the length ([00127]).

With respect to claims 14-17 and 19-27, note rejection of claim 13 above.

Allowable Subject Matter

Claims 3-5 and 43-45 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The following is a statement of reasons for the indication of allowable subject matter: The combination of the forehead pad wherein the support post projects from the

first surface of the base portion at an angle, wherein the angle is defined between a tangent to the first surface at a point of contact between the support post and the base portion and wherein the angle is between about 60° and about 120° is neither anticipated nor rendered obvious by the prior art of record.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The balance of art is cited to show forehead supports: 2005/0011522.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Teena Mitchell whose telephone number is (571) 272-4798. The examiner can normally be reached on Monday-Friday however on a flexible schedule.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry Bennett can be reached on (571) 272-4791. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Teena Mitchell Examiner Art Unit 3743 June 21, 2005 Page 18